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Prequalification Unit Inspection Services
WHO INSPECTION REPORT
(WHOPIR)
Desk Assessment of Finished Product Manufacturer

Part 1	**General information**
Company information	
Name of Manufacturer	Ajanta Pharma Limited
Corporate address of manufacturer	Ajanta Pharma Limited Ajanta House, Charkop Kandivli (West) Mumbai, 400 067 India Tel: +91- 22-66061000 Fax: +91-22 66061200/ 66061300
Contact person	Mr A.V. Jayakumar Executive Vice-President, Corporate Quality jayakumar.av@ajantapharma.com Tel: +91 954 5511337
Inspected site	
Name & address of manufacturing site	Ajanta Pharma Limited Z/103/A, Dahej SEZ-II, Bharuch, Gujarat 392130, India. Tel: +91-2641 275500 Fax: +91-2641 253053 Latitude: 21.680766 Longitude: 72.553326 DUNS number: 86-219-9968
Production Block/Unit	Not applicable
Manufacturing license number	1. The GMP certificate, 21062594, issued to the manufacturing License No G/25/2080 on 14/6/2021 by the Food and Drugs Administration, Gandhinagar, Gujarat State, is valid until 13/6/2024. 2. Manufacturing and Export License number No G/25/2080 issued on 12/02/2020 by the Food and Drugs Administration, Gandhinagar, Gujarat State valid from 23 February 2020 to 22 February 2025.
Desk assessment details	
Start and end dates of review	7-8 December 2023
Inspection record number	INSP-FPP-2020-0085
Products covered by this desk assessment	

PQT Number	Finished Pharmaceutical Product	Prequalification status
MA111	Artemether/Lumefantrine Tablet 20mg/120mg	Prequalified
MA130	Artemether/Lumefantrine Tablet 80mg/480mg	Prequalified
MA092	Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg	Prequalified
MA128	Artemether/Lumefantrine Tablet 40mg/240mg	Prequalified
MA129	Artemether/Lumefantrine Tablet 60mg/360mg	Prequalified

Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments**	
FDA, USA	Dates of inspection:	5-9 September 2022
	Type of inspection:	Pre-approval inspection for 3 product applications
	Block/Unit:	Not applicable
	Type of products/Dosage forms covered:	Dosage forms covered: • Extended-release tablets • Delayed release tablets • Delayed release oral suspension
FDA, USA	Dates of inspection:	17 – 22 June 2019
	Type of inspection:	GMP and Pre-approval inspection for product applications
	Block/Unit:	Not Applicable
	Type of products/Dosage forms covered:	Delayed-Release Capsules / Capsules
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	A Desk assessment of the site was performed from 15th May to 12th June 2020 and the following inspection reports were reviewed: USFDA, dates of inspection 17-22 June 2019, 23-27 July 2018 and 3-7 April 2017. WHO inspection 7-11 August 2017. This desk assessment concluded, "*Based on the previous WHO inspections and on the GMP evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site* ***Ajanta Pharma Ltd,*** *located* ***at Z/103/A, Dahej SEZ-II, Bharuch, Gujarat 392130, India,*** *is considered to be operating at an acceptable level of compliance with WHO GMP guidelines. This compliance status shall be valid until 01 August 2022 or when WHO conducts another inspection or a stringent regulatory authority".* The last WHO on-site inspection was performed from7 August to 11 August 2017. It closed out on 11 September 2017, and concluded that, following the submission and assessment of the CAPAs, this site was considered to be operating at an acceptable level of compliance with WHO GMP guidelines.	
Summary of manufacturing activities	The site is involved in manufacturing, packaging, quality control, stability testing, storage and distribution of: • Tablets (coated and un-coated) • Capsules • Oral powders Toxic or hazardous products, such as β-lactams, cytotoxic drugs, hormones, and steroids, were not manufactured at the site.	
General information about the company and manufacturing site	Ajanta Pharma Limited was incorporated in 1973 and is involved in the manufacturing and marketing pharmaceutical products for the Indian and international markets with manufacturing plants in India and overseas. The Ajanta global headquarters and corporate office is located in Kandivali, Mumbai. Ajanta employs over 7'000 personnel worldwide (including India) with staff involved in sales, marketing, Research and Development (R&D), manufacturing, quality, regulatory, human resources, accounts, finance, secretarial, legal, administration and various other functions. Ajanta has several branded generic products in India with therapeutic classes that focus on cardiology, ophthalmology, dermatology, musculoskeletal and	

	Over-the-counter (OTC) segments. Ajanta's products are developed at the Research and Development (R&D) centre in Kandivali, Mumbai, India. Ajanta has seven manufacturing facilities, six formulation facilities and one Active Pharmaceutical Ingredient (API) facility.
Focus of the last WHO inspection	The last WHO on-site inspection was conducted from 7 to 11 August 2017 and covered sections of the WHO GMP for non-sterile products, including quality assurance, premises, equipment, documentation, validation, production, and manufacture. A Desk assessment was conducted from 15 May to 12 June 2020 , considering the US FDA on-site inspection conducted from 17 to 22 June 2019, which covered cGMP principles and the product applications for extended-release tablets, delayed-release tablets, tablets, and capsules.
Areas inspected	During the last WHO on-site inspection (7 - 11 August 2017), the following areas were covered: • Quality Assurance • Qualification and validation • Complaints • Recalls • Contracts • Premises • Equipment • Documentation • Production • Quality control
Out of scope and restrictions (last WHO inspection)	Non-WHO prequalified products
WHO products covered by the last WHO inspection	The onsite inspection of 2017 covered the following products: **PQT Number** | **Finished Pharmaceutical Product** MA092 | Artemether / Lumefantrine Tablet, Dispersible 20mg/120mg MA111 | Artemether/Lumefantrine Tablet 20mg/120mg
Additional products to be covered by this desk assessment:	No new products were covered by the desk assessment.
Abbreviations	**Meaning**
AHU	Air handling unit
API	Active pharmaceutical ingredient
BMR	Batch manufacturing record
BPR	Batch production record
CAPA	Corrective and preventive action
CC	Change control
FPP	Finished pharmaceutical product
GMP	Good manufacturing practices
NC	Non-conformity
NRA	National regulatory agency
PQR	Product quality review
PQS	Pharmaceutical quality system

QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
SMF	Site master file
SOP	Standard operating procedure

Part 4	**Summary of the assessment of supporting documentation**

a) List of all regulatory inspections performed in the period 2020-2022 and their outcomes:

#	Inspection Date	Regulatory Authority /Type of inspection	Report Certificate Date	Outcomes
1.	15th May to 12th Jun 2020	WHO – Desk Assessment	12th Jun 2020	Approved
2.	5th and 9th Sep 2022	United States Food and Drug Administration (USFDA)	9th Nov 2022	Approved
3.	25th Sep 2020	Central Drug Standards Control Organization (CDSCO), India	21st Oct 2020	Approved
4.	8th to 12th Feb 2021	Medicines Control Authority of Zimbabwe (MCAZ), Zimbabwe	18th Oct 2021	Approved
5.	27th to 28th May 2021	Food & Drug Administration, Gujarat	14th Jun 2021	Approved
6.	11th to 14th Apr 2022	Zambia Medicines Regulatory Authority (ZAMRA)	06th Jul 2022	Approved
7.	9th and 10th June 2022	Ministry of Health, Pharmacy and Poisons Board (PPB), Kenya	10th Jun 2022	Approved
8.	11th Nov 2022	DPML Cameroon	N/A	Approved

b) Manufacturing authorization granted by national authorities:

1. The GMP certificate, 21062594, along with the manufacturing License No. G/25/2080, issued on 14/6/2021 by the Food and Drugs Administration, Gandhinagar, Gujarat State, is valid until 13/6/2024.
2. Manufacturing and Export License number No G/25/2080 issued on 12/02/2020 by the Food and Drugs Administration, Gandhinagar, Gujarat State, valid till 22 February 2025.

c) Site master file:

SMF: DHJ/SMF/001, version 08, effective 29 August 2022, was reviewed. No objectionable observations were made.

d) List of all the products and dosage forms manufactured on-site:

The list was provided and reviewed as part of the desk assessment.

e) Most recent product quality review(s) (PQR)(s) of the concerned WHO product(s):

The following PQRs submitted as part of the Desk Assessment request were reviewed:

1. Artemether/Lumefantrine Tablet, 20mg/120mg PQR/DHJ/21-22/006 April 2021 – March 2022:
   - 177 batches manufactured
   - 15 OOS and 4 OOT. All OOS and OOT were investigated and closed, and necessary actions were taken.
   - 9 deviations. All deviations were investigated, closed and necessary action taken.
   - 18 Change Controls (CC). All changes were reviewed for impact and approved.
   - No complaints/recalls/returns/reprocessed or reworked batches
   - Stability: Product was placed on long term 25°C/60%RH and Accelerated 40°C/75%RH conditions. The product was found to be compliant.

2. Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg PQR/DHJ/21-22/007 April 2021 – March 2022:
   - 66 batches manufactured
   - 6 OOS and 8 OOT. All OOS and OOT were investigated and closed, and necessary actions were taken.
   - 1 deviation. All deviations were investigated, closed and necessary action taken.
   - 26 CC. All changes were reviewed for impact and approved.
   - No complaints/recalls/returns/reprocessed or reworked batches
   - Stability: Product was placed on long term 25°C/60%RH and Accelerated 40°C/75%RH conditions. The product was found to be compliant.

3. Artemether/Lumefantrine Tablet, 40mg/240mg PQR/DHJ/21-22/008 April 2021 – March 2022:
   - No batches manufactured during the review period
   - No batches were released during the review period.
   - No OOS and No OOT.
   - No deviations.
   - 9 CC. All changes were reviewed for impact and approved.
   - No complaints/recalls/returns/reprocessed or reworked batches
   - Stability: Product was placed on long term 25°C/60%RH and Accelerated 40°C/75%RH conditions. The product was found to be compliant.

4. Artemether/Lumefantrine Tablet, 60mg/360mg PQR/DHJ/21-22/009 April 2021 – March 2022:
   - No batches manufactured during the review period
   - No batches were released during the review period.
   - No OOS and No OOT.
   - No deviations.
   - 10 CC. All changes were reviewed for impact and approved.
   - No complaints/recalls/returns/reprocessed or reworked batches
   - Stability: Product was placed on long term 25°C/60%RH and Accelerated 40°C/75%RH conditions. The product was found to be compliant.

5. Artemether/Lumefantrine Tablet, 80mg/480mg PQR/DHJ/21-22/010 April 2021 – March 2022:
   - No batches manufactured during the review period
   - No batches were released during the review period.
   - No OOS and No OOT.
   - No deviations.
   - 8 CC. All changes were reviewed for impact and approved.
   - No complaints/recalls/returns/reprocessed or reworked batches

- Stability: Product was placed on long term 25°C/60%RH and Accelerated 40°C/75%RH conditions. The product was found to be compliant.

The assessment of the five QPRs did not raise any questionable objectives.

f) Batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of relevant product(s):
A couple of batch manufacturing and packaging records were submitted as part of the Desk Assessment request and were reviewed.

The assessment of the 2 BMR and BPR and the applicable analytical records did not raise any questionable objectives.

g) Master batch manufacturing and packaging record(s) of the product(s) of interest:
The following Master batch manufacturing and packaging records were submitted as part of the Desk Assessment request and were reviewed:

1. BMR Artemether 20 mg + Lumefantrine 120 mg Dispersible Tablets
2. BPR Artemether 20 mg + Lumefantrine 120 mg Dispersible Tablets
3. BMR Artemether 20 mg + Lumefantrine 120 mg Tablets
4. BPR Artemether 20 mg + Lumefantrine 120 mg Tablets
5. BMR Artemether 80 mg + Lumefantrine 480 mg Tablets; product yet to be commercialized
6. BPR Artemether 80 mg + Lumefantrine 480 mg Tablets; product yet to be commercialized
7. BMR Artemether 40 mg + Lumefantrine 240 mg Tablets; no batches were manufactured yet
8. BMR Artemether 60 mg + Lumefantrine 360 Tablets; no batches were manufactured yet

The 8 BMR and BPR assessments did not raise any questionable objectives.

h) If any of the products are sterile, the completed batch records for the most recent media fill validation that is relevant to the product(s) of interest and report on its outcome:
Not applicable.

i) Recalls in the past three years related to products with quality defects:
A declaration was submitted and signed on 2 December 2022 stating that no product recall has been initiated during the past 3 years.

j) Confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the product(s) has been performed and all matters dealt with:
A declaration was submitted that a full self-inspection or external audit dedicated to the products has been performed and that all matters have been dealt with.

k) Copy of any warning letter, or equivalent regulatory action, issued by any authority to which the site provides or has applied to provide the product:
A declaration was submitted and signed on 2 December 2022 stating that no notice of concern (NOC), warning letters, or equivalency regulatory actions were issued.

l) Out-of-stock situations:
A declaration was submitted and signed on 30 November 2022 stating that no out-of-stock situations had occurred during the past three years and that no out-of-stock situation is foreseen for the future.

m) Additional documents submitted:

Not Applicable

Part 5	Conclusion – Desk assessment outcome

Based on the previous WHO inspections and on the GMP evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site **Ajanta Pharma Limited, located Z/103/A, Dahej SEZ-II, Bharuch, Gujarat 392130, India**, is considered to be operating at an acceptable level of compliance with WHO GMP guidelines.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted by this period is positive.

Part 6	List of guidelines referenced in this inspection report

1. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eight Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2.
   Short name: WHO TRS No. 986, Annex 2
   https://www.who.int/publications/m/item/trs986-annex2

2. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2.
   Short name: WHO TRS No. 957, Annex 2
   https://www.who.int/publications/m/item/annex-2-trs-957

3. WHO guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report. Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 9.
   Short name: WHO TRS 1010, Annex 9
   https://www.who.int/publications/m/item/trs1010-annex9

4. WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 3.
   Short name: WHO TRS No. 1033, Annex 3
   https://www.who.int/publications/m/item/annex-3-trs-1033

5. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4.
   Short name: WHO TRS No. 929, Annex 4
   https://www.who.int/publications/m/item/annex-4-trs-929

6. WHO good practices for pharmaceutical quality control laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1.
   Short name: WHO TRS No. 957, Annex 1

https://www.who.int/publications/m/item/trs957-annex1

7. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 3.
Short name: WHO TRS No. 957, Annex 3
https://www.who.int/publications/m/item/trs957-annex3

8. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty Second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8.
Short name: WHO TRS No. 1010, Annex 8
https://www.who.int/publications/m/item/Annex-8-trs-1010

9. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Third Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1019), Annex 2.
Short name: WHO TRS No. 1019, Annex 2
https://www.who.int/publications/m/item/trs1019-annex2

10. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
Short name: WHO TRS No. 1044, Annex 4
https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/production/trs1044-annex4-technology-transfer-in-pharmaceutical-manufacturing.pdf

11. WHO good manufacturing practices for sterile pharmaceutical products. Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
Short name: WHO TRS No. 1044, Annex 2
https://www.who.int/publications/m/item/trs1044-annex2

12. General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-First Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3. ***Short name: WHO TRS No. 943, Annex 3***
https://www.who.int/publications/m/item/trs943-annex3

13. WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2.
Short name: WHO TRS No. 961, Annex 2
https://www.who.int/publications/m/item/trs961-annex2

14. WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2.

Short name: WHO TRS No. 981, Annex 2
https://www.who.int/publications/m/item/trs981-annex2

15. WHO guidelines on variation to a prequalified product. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 3.
Short name: WHO TRS No. 981, Annex 3
https://www.who.int/publications/m/item/annex-3-trs-981

16. WHO guidelines for drafting a site master file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14.
Short name: WHO TRS No. 961, Annex 14
https://www.who.int/publications/m/item/tr961-annex14

17. Good Manufacturing Practices: Guidelines on validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Third Report Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 3.
Short name: WHO TRS No. 1019, Annex 3
https://www.who.int/publications/m/item/trs1019-annex3

18. WHO General guidance on hold-time studies WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4.
Short name: WHO TRS No. 992, Annex 4
https://www.who.int/publications/m/item/trs992-annex4

19. Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9.
Short name: WHO TRS No. 961, Annex 9
https://www.who.int/publications/m/item/trs961-annex9-modelguidanceforstoragetransport

20. WHO Technical supplements to Model Guidance for storage and transport of time – and temperature – sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5.
Short name: WHO TRS No. 992, Annex 5
https://www.who.int/publications/m/item/trs992-annex5

21. WHO Recommendations for quality requirements when plant – derived artemisinin is used as a starting material in the production of antimalarial active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 6.
Short name: WHO TRS No. 992, Annex 6
https://www.who.int/publications/m/item/trs-992-annex-6

22. Guideline on data integrity. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 4.
Short name: WHO TRS No. 1033, Annex 4

https://www.who.int/publications/m/item/annex-4-trs-1033

23. WHO general guidance on variations to multisource pharmaceutical products. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 10.
Short name: WHO TRS No. 996, Annex 10
https://www.who.int/publications/m/item/trs966-annex10
24. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 10. ***Short name: WHO TRS No. 1010, Annex 10***
https://www.who.int/publications/m/item/trs1010-annex10

25. Points to consider when including Health-Based Exposure Limits in cleaning validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 2.
Short name: WHO TRS No. 1033, Annex 2
https://www.who.int/publications/m/item/annex-2-trs-1033

26. Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fourth Report Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 6.
Short name: WHO TRS No. 1025, Annex 6
https://www.who.int/publications/m/item/trs-1025-annex-6

27. Production of water for injection by means other than distillation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 3.
Short name: WHO TRS No. 1025, Annex 3
https://www.who.int/publications/m/item/trs-1025-annex-3-water-for-injection

27. Good chromatography practice. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 4.
Short name: WHO TRS No. 1025, Annex 4
https://www.who.int/publications/m/item/trs1025-annex4